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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/996,056	11/27/2001	Alice A. Jacobs	12877-006001	1285

26161 7590 10/06/2003

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EXAMINER

SIEW, JEFFREY

ART UNIT	PAPER NUMBER
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1637

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DATE MAILED: 10/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/996,056

Applicant(s)

JACOBS ET AL.

Examiner

Jeffrey Siew

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 20 June 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.
- 4a) Of the above claim(s) 26-31 is/are withdrawn from consideration.
- 5) ☐ Claim(s) 1-25, 32-34 is/are allowed.
- 6) ☒ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-34 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 06 May 2002 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 4.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 1-25,32-34 drawn to method of determining cause of medical symptoms, classified in class 435, subclass 6.
  - II. Claims 26-28, drawn to device with micromixer and array, classified in class 435, subclass 285.1.
  - III. Claims 29-31, drawn to array with linkers, classified in class 435, subclass 287.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions Group I,II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions Group II is drawn to device with a micromixer which is not required in Group I or III. Group III involves the use of linkers which are not required in Group I and II.

During a telephone conversation with Mr. Fosse on June 20, 2003 a provisional election was made with traverse to prosecute the invention of Group I, claims 1-25,32-34 . Affirmation of this election must be made by applicant in replying to this Office action. Claims 26-31 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

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Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

### ***Specification***

2. Figures 18A & 18B are designated in the Drawings but the specification only refers to Figure 18. Proper designation of the figures is required. Similarly Figures 34D & 34E are located in the drawings but the specification only refers to Figures 34A-C. Proper correction is required.

### ***Drawings***

3. At the time of this examination Figures 38A-D could not be located in the drawings filed 3/28/03. Replacement is required.

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***Claim Rejections - 35 USC § 102***

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-8,10,12-17,18-20,24-25,32-34 are rejected under 35 U.S.C. 102(b) as being anticipated by Balch (US6,083,763 July 4, 2000).

Balch teach a method of determining cause of one or more medical symptoms by obtaining a biological sample from subject, obtaining an array of different probes that selectively interact with target associated with different known cause of one or medical symptoms, applying sample to probes so they interact, detecting and analyzing and the device and system of using such an array (see whole document esp. abstract, col.5 lines 16-30, particularly col. 8 & col. 34 lines 5-12). They teach the use of probes which are nucleic acids, antigens or antibodies (see col.1 lines 25-30). They teach testing human sample or DNA (see col. 33 line 57 & 66). They teach use of thiol or amino groups for covalent binding of ligands (see col. 21 line 35-40).

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 9 & 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (US6,083,763 July 4, 2000) in view of Au-Young et al (US6,309,821 Oct. 30, 2001).

The teachings of Balch are described previously.

Balch do not teach deceased sample or biopsies.

Au-Young teach testing autopsy biopsies to detect disease related nucleic acids (see col. 14 lines 40-50).

One of ordinary skill in the art would have been motivated to apply Au-Young et al's teachings of autopsied biopsies to Balch's assay in order to detect disease agents post mortem. It was well known and commonly practiced in the art to test samples from deceased individuals to confirm and diagnose diseases. As Au-Young et al teach testing samples from autopsied biopsies from serum, amniotic fluid or muscle samples, it would have been prima facie obvious to apply Au-Young et al's teaching of testing samples from deceased individuals to Balch's detection method in order to confirm and diagnose the causative diseases in expired individuals.

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6. Claims 21-23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Balch (US6,083,763 July 4, 2000) in view of Persing et al (US5,643,723 July 1, 1997).

The teachings of Balch are described previously.

Balch do not teach therapeutic optimization factor.

Persing et al teach detecting M. tuberculosis mutants particularly rifampin resistant by using probes that target rpOB (see whole doc. esp. abstract).

One of ordinary skill in the art would have motivated to apply Persing et al's teachings of detecting drug resistance genes to Balch's detection method in order to detect patients who have drug resistance pathogens. It would have been prima facie obvious to detect drug resistance in pathogens as taught by Persing et al in order to correctly confirm disease diagnosis such as TB and provide correct drug regimen.

### SUMMARY

7. No claims allowed.

### CONCLUSION


8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Siew whose telephone number is (703) 305-3886 and

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whose e-mail address is Jeffrey.Siew@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route. The examiner is on flex-time schedule and can best be reached on weekdays from 6:30 a.m. to 3 p.m. If attempts to reach the examiner are unsuccessful, the examiner's supervisor, Gary Benzion, can be reached on (703)-308-1119.

Any inquiry of a general nature, matching or filed papers or relating to the status of this application or proceeding should be directed to the Tracey Johnson for Art Unit 1637 whose telephone number is (703)-305-2982.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Center numbers for Group 1600 are Voice (703) 308-3290 and FAX (703)-308-4242.

  
JEFFREY SIEW  
PRIMARY EXAMINER

September 27, 2003